

**MINUTES OF 247th MEETING OF CENTRAL LICENSING BOARD
HELD ON FRIDAY 29th April, 2016**

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247th meeting of the Central Licensing Board (CLB) was held on Friday 29th April, 2016 in the Division of Drug Licensing, Drug Regulatory Authority of Pakistan, 3rd Floor, TF Complex, G-9/4, Islamabad under the Chairmanship of Mr. Faqeer Muhammad Shaikh, Director Drug Licensing, DRAP.

Following members attended the meeting: -

| S. No. | Name & Designation | Status |
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| 1. | Representative of Division of Quality Assurance and Laboratory Testing, DRAP, Islamabad. (Mr. Zeeshan Nazir, DDC, QA attended as representative of QA/LT Division) | Member |
| 2. | Dr. Zaka-ur-Rehman, Chief Drug Controller, Department of Health, Govt. of Punjab. | Member |
| 3. | Mr. Qaiser Muhammad, Chief Drug Inspector, Department of Health, Govt. of Sindh. | Member |
| 4. | Mr. Afrasiyab, Chief Drug Inspector, Department of Health, Govt. of Khyber Pakhtunkhwa. | Member |
| 5. | Syed Muied Ahmed, Expert in manufacturing of drugs. | Member |
| 6. | Dr. Ikram-ul-Haq, QC/QA Expert | Member |
| 7. | Syed Jawed Yousaf Bukhari, QC/QA Expert | Member |
| 8. | Prof. Dr. Muhammad Saeed, Professor of Pharmacy | Member |
| 9. | Mr. Khurram Shahzad Mughal, Consultant M/o Law, Justice and Human Rights, as representative of M/o Law, Justice and Human Rights, Islamabad. | Member |
| 10. | Mr. Abdullah, Deputy Director General (Lic.), DRAP, Islamabad. | Secretary |
| 11. | Mr. Khalid Munir, Chief Executive, Trigon Pharmaceuticals (Pvt) Ltd., & Ms. Mahvash Siddiqi, Chief Operating Officer Epla Laboratories (Pvt) Ltd., as Representative of PPMA | Observer |
| 12. | Mr. Nadeem Alamgir, Representative of Pharma Bureau. | Observer |
| 13. | Mr. Kamran Anwar, Secretary General PCDA , representative of PCDA | Observer |

The Chairman CLB welcomed the honorable members of this Apex Forum & participants of the meeting. The meeting started with the recitation of verses from the Holy Quran.

The Chairman apprised the members of the Board that proceedings of CLB shall be conducted in an amicable and responsible way to deliver to the public and stake holders in a transparent and efficient manner. Quality shall be given priority and there shall be zero tolerance.

He further added that all the legal and codal formalities regarding convening of the meeting have been fulfilled. Mr. Adnan Faisal Saim DDC (QC) & Dr. Akbar Ali ADC (Lic.) DRAP Islamabad assisted the Secretary CLB in presenting the agenda.

LICENSING DIVISION

Item-I CONFIRMATION OF THE MINUTES OF 246th MEETING

The Central Licensing Board (CLB) formally confirmed the minutes of its 246th meeting held on Monday 22nd February, 2016.

Item-II: GRANT OF NEW DRUG MANUFACTURING LICENSES.

The Board considered the following cases of grant of new drug manufacturing license in the light of recommendations of respective panel of experts/inspectors and decided as under:

| S# | Name of the firm | Date of Inspection / Type of License | Decision of CLB |
|-----------|---|---|--|
| 1. | M/s Scilife Pharma (Pvt) Ltd, Plot No. FD-57/58-A-2, Korangi Creek, Industrial Park (KCIP) Karachi. | 29-03-2016 Formulation | The Board approved the grant of DML by way of formulation with following five sections: <u>Sections (05)</u> 1. Tablet (General) 2. Capsule (General) 3. Sachet (General) 4. Cream Ointment (General) 5. Dry Suspension Oral (General) |
| 2. | M/s Vikor Healthcare (Pvt) Ltd, Plot No. C-126 to C-135 Hub Industrial Trading Estate, Hub District Lasbela, Baluchistan. | 04-04-2016 & 05-04-2016 Formulation | The Board approved the grant of DML by way of formulation with following three sections: <u>Sections (03)</u> 1. Catgut Suture (Absorbable). 2. Silk Suture (Non Absorbable). 3. Synthetic Suture (Absorbable & Non Absorbable). |
| 3. | M/s Vikor Healthcare (Pvt) Ltd, Plot No. C-126 to C-135 Hub Industrial Trading Estate, Hub District Lasbela, Baluchistan. | 04-04-2016 & 05-04-2016 Basic Manufacturing | The Board approved the grant of DML by way of Basic Manufacture with following one section: <u>Section (01)</u> Catgut Strings (Raw Surgical Sutures). |
| 4. | M/s. Cunningham Pharmaceuticals (Pvt) Ltd, Plot No. 81, Sunder Industrial Estate, Lahore. | 17-03-2016 Formulation | The Board approved the grant of DML by way of formulation with following seven sections: <u>Sections (07)</u> 1. Tablet (General) 2. Capsule (General) 3. Sachet (General) 4. Liquid Ampoule (General) 5. Capsule (Cephalosporin) 6. Dry Powder Suspension (Cephalosporin). 7. Dry Powder Injection (Cephalosporin). |

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| 5. | M/s. Jupiter Pharma, Plot No.S-6, National Industrial Zone, RCCI, Rawat, Rawalpindi. | 20-04-2016 Formulation | The Board approved the grant of DML by way of formulation with following three sections: <u>Sections (03)</u> 1. Tablet (General) 2. Capsule (General) 3. Dry Powder Suspension (General). |
| 6. | M/s. Medipak Limited, Plot No. 554, Sunder Industrial Estate, Lahore. | 16-03-2016 Formulation | The Board approved the grant of DML by way of formulation with following one section: <u>Section (01)</u> Intravenous Infusion |
| 7. | M/s. Vantage Pharmaceutical, situated at 54-RB Sarhali, 6-KM, Sangla Hill Shakhot Road, District, Faisalabad. | 19-04-2016 Formulation | The Board approved the grant of DML by way of formulation with following two sections: <u>Sections (02):</u> 1. Oral Powder (Veterinary) 2. Oral Liquid (Veterinary). |
| 8. | M/s. Regal Pharmaceuticals, Plot No. A2, Street No. S-5, National Industrial zone, RCCI, Rawat, Rawalpindi. | 26-04-2016 Formulation | The Board approved the grant of DML by way of formulation with following six sections: <u>Sections (06)</u> 1. Tablet (General) 2. Capsule (General) 3. Dry Powder for suspension (General) 4. Oral Liquid (General) 5. Liquid Ampoule (General) 6. Liquid Vial Injectable (General) |

Item-III: GRANT OF ADDITIONAL SECTIONS/EXPANSION/AMENDMENTS IN LOPs ETC.

The Board considered following cases of Grant of Additional Sections & Expansion/Amendments in Layout Plans (LOPs) etc of already licensed units in the light of recommendations by respective panel of experts/inspectors and decided as under: -

| S# | Name of the firm | Date of Inspection / Type of License | Decision of CLB |
|-----------|---|---|---|
| 1. | M/s S.J & G Fazul Ellahie, E-46, SITE, Karachi. DML No. 000083 (Formulation) | 01-03-2016 | The Board approved the grant of one additional section as under:- <u>Section (01):</u> 1. Dry Powder Injection (Carbapenem) |
| 2. | M/s Hilton Pharma (Pvt) Ltd, Plot No. 13&14 Sector 15, Korangi Industrial Area, Karachi. DML No. 000136 (Formulation) | 09-04-2016 | The Board approved the grant of one additional section as under:- <u>Section (01):</u> 1. Tablet (Psychotropic) |

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| 3. | M/s Abbott Laboratories Pakistan Ltd, Landhi, Karachi DML No. 000001 (Formulation) | 15-02-2016 | The Board approved the grant of expansion in already existing section as under:- <u>Section (01):</u> 1. Injection (SVP) - Expansion |
| 4. | M/s Wnsfield Pharmaceutical, plot No. 122, Block-A, Phase-V, Industrial Estate, Hattar, DML No. 000610 (Formulation) | 05-03-2016 | The Board approved the grant of two additional sections as under:- <u>Sections (02):</u> 1. Cream / Ointment / Gel (General). 2. Sachet (Cephalosporin) |
| 5. | M/s News Pharma, 42, Sunder Industrial Estate, Lahore. DML No. 000775 (Formulation) | 06-04-2016 | The Board approved the grant of one additional section as under:- <u>Section (01):</u> 1. Dry Powder Injection (Cephalosporin) |
| 6. | M/s Vision Pharmaceuticals, Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad. DML No. 000517 (Formulation) | 28-04-2016 | The Board approved the grant of three additional sections as under:- <u>Sections (03)</u> 1. Liquid Ampoule (General) 2. Liquid vial (General) 3. Dry Powder Injection (Steroids) |

Item-IV: GRANT OF RENEWAL OF DRUG MANUFACTURING LICENSE.

The Board considered the following cases of Grant of Renewal of Drug Manufacturing Licenses in the light of recommendations by panel of experts/inspectors subject to confirmation of deposition of CRF as admissible under the rules and decided as under: -

| S. No | Name of the firm | Date of Inspection / Type of License | Decision of CLB |
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| 1. | M/s Barrett Hodgson Pakistan (Pvt) Ltd, SITE, Karachi. DML No. 000457 (Formulation) | 18-21-2016 & 02-02-2016 | The Board approved the renewal of DML for following sections as per recommendations of panel: <u>Sections (11): -</u> 1) Oral Syrup / Suspension. 2) Liquid Injection. 3) Ointment (General). 4) Capsule (General). 5) Tablet (General). 6) Dry Suspension (General). 7) Sachet (General). 8) Ophthalmic / Ear drops. 9) Capsule (Cephalosporin) 10) Cephalosporin (Suspension) 11) Cephalosporin (Injection) |

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| 2. | <p>M/s Zanco Pharmaceutical Laboratories, Plot No. F/4, SITE, Hyderabad.</p> <p>DML No. 000251 (Formulation)</p> | 04-02-2016 | <p>The Board approved the renewal of DML for following sections as per recommendations of panel:</p> <p>Sections (11): -</p> <ol style="list-style-type: none"> 1) Syrup (General). 2) Tablet (General). 3) Ointment / Cream/ Gel (General). 4) External preparation (mouth wash) 5) Capsule (General). 6) Tablet General (Antibiotic) 7) Capsule General (Antibiotic) 8) Sachet (General). 9) Tablet (Psychotropic). 10) Dry Powder (Cephalosporin). 11) Capsule (Cephalosporin). |
| 3. | <p>M/s Helix Pharma (Pvt) Ltd, A-56, SITE, Karachi.</p> <p>DML No. 000030 (Formulation)</p> | 17-02-2016 | <p>The Board observed that:-</p> <ul style="list-style-type: none"> • the report was not candid and clear and observations were not reported in the panel inspection report and evaluation proforma was also not provided with the inspection report. • the panel has informed the observations made during inspection to the firm but did not submit to the Central Licensing Board in writing. <p>Keeping in view, the above observations the Board considered and deferred the renewal of DML for re-inspection by same panel and further directed to submit clear and candid report as per rules.</p> |

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| 4. | <p>M/s S.J & G Fazul Ellahie, E-46, SITE, Karachi.</p> <p>DML No. 000083 (Formulation)</p> | 01-03-2016 | <p>The Board approved the renewal of DML for following sections as per recommendations of panel:</p> <p><u>Sections (13):</u></p> <ol style="list-style-type: none"> 1) Liquid Injectable (Ampoule, Vial & Infusion). 2) Tablet (General). 3) Capsule (General). 4) Powder Injectable (Cephalosporin). 5) Dry Suspension (Cephalosporin). 6) Tablet (Cephalosporin). 7) Capsule (Cephalosporin). 8) Dry Suspension (General). 9) Ointment / Cream. 10) Oral Liquid (Syrup / Suspension). 11) Eye / Ear drops. 12) Lyophilization (Sterile area) powder Injection General. 13) Liquid Injection (Veterinary). <p>The Board further deferred the renewal of DML for following sections as the firm was underway of upgradation and improvements of the said sections:</p> <ol style="list-style-type: none"> 1) Oral Liquid (Veterinary). 2) Oral Powder (Veterinary). 3) Tablet (Veterinary). <p>The Board further directed the firm not to conduct the manufacturing operations till up-gradation, re-inspection and approval of renewal of above three sections by Central Licensing Board.</p> |
| 5. | <p>M/s Epla Laboratories (Pvt) Ltd, D-12, Estate Avenue, SITE, Karachi.</p> <p>DML No. 000071 (Formulation)</p> | 03-03-2016 | <p>The Board approved the renewal of DML for following sections as per recommendations of panel:</p> <p><u>Sections (10): -</u></p> <ol style="list-style-type: none"> 1) Tablet. 2) Liquid. 3) Ointment / Cream. 4) Dry Powder (General). 5) Encapsulation. 6) Nasal Solution. 7) Dry Powder Suspension (Beta Lactum) 8) Encapsulation (Beta Lactum) 9) Oral Liquid (Veterinary) 10) Dry Powder (Veterinary) |
| 6. | <p>M/s Aspin Pharma (Pvt) Ltd, Plot No. 10&25 Sector 20, Korangi Industrial Area, Karachi.</p> <p>DML No. 000045 (Formulation)</p> | 21-03-2016 | <p>The Board approved the renewal of DML for following sections as per recommendations of panel:</p> <p><u>Sections (4): -</u></p> <ol style="list-style-type: none"> 1) Tablet (General). 2) Capsule (General). 3) Liquid Syrup 4) Ointment / Cream. |

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| 7. | M/s Sanofi Aventis Pakistan Limited, Plot No. 23 Sector 22, Korangi Industrial Area, Karachi. DML No. 000007 (Formulation) | 22-03-2016 | The Board approved the renewal of DML for following sections as per recommendations of panel: <u>Sections (8): -</u> 1) Injectable Dry Powder (Cephalosporin). 2) Tablet. 3) Capsule. 4) Cream & Gel. 5) Dry Powder Sachet. 6) Dry Powder Suspension. 7) Liquid (Syrup Suspension) 8) Sterile Injectable (Ampoule & Vial). |
| 8. | M/s Sanofi Aventis Pakistan Limited, Plot No. 23 Sector 22, Korangi Industrial Area, Karachi. DML No. 000368 (Basic Manufacturing) | 24-03-2016 | The Board approved the renewal of DML for following sections as per recommendations of panel: <u>Section (1): -</u> Polygeline (Haemaccel). |
| 9. | M/s Adamjee Pharmaceutical (Pvt) Ltd, Plot No. 36 Sector 15, Korangi Industrial Area, Karachi. DML No. 000236 (Formulation) | 02-04-2016 | The Board approved the renewal of DML for following sections as per recommendations of panel: <u>Sections (7): -</u> 1) Tablet (General) 2) Tablet (Psychotropic / Neuroleptic) 3) Capsules (General / Antibiotic) 4) Capsule (Cephalosporin) 5) Dry Powder Suspension (General) 6) Dry Powder Suspension (Cephalosporin) 7) Liquid Syrup. |
| 10. | M/s. Symans Pharmaceuticals (Pvt) Ltd, 10-KM, Sheikhpura Road, Lahore. DML No. 000323 (Formulation) | 02-04-2016 | The Board observed that the panel has conducted the inspection for the elapsed renewal period i.e. from 19-10-2010 to 18-10-2015 and recommended the renewal of DML for the said period. The Board considered and endorsed the approval of renewal of DML for the period from 19-10-2010 to 18-10-2015. |
| 11. | M/s. Platinum Pharmaceuticals (Pvt) Ltd, A-20, North West Industries Zone, Bin Qasim, Karachi. DML No. 000415 (Formulation) | 15, 16, 18 & 30 April, 2016 | The Board approved the renewal of DML for following sections as per recommendations of panel: <u>Sections (15): -</u> 1. Oral Liquid (General) 2. Mouth Wash (General) 3. Tablet (General). |

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| | | | <ul style="list-style-type: none"> 4. Capsule (General). 5. Cream / Ointment / Gel (General). 6. Sachet (General). 7. Dry Powder Suspension (General). 8. Capsule (Hormone). 9. Tablet (Hormone). 10. Cream (Hormone). 11. Nasal Spray (Hormone). 12. Capsule (Cephalosporin) 13. Tablet (Cephalosporin) 14. Dry Powder Suspension (Cephalosporin). 15. Inhaler /Aerosol. |
| 12. | <p>M/s Makson Pharmaceutical, Plot No. 80-B, Street No. 6, Sector I-10/3, Industrial Area, Islamabad.</p> <p>DML No. 000560 (Formulation)</p> | 25-01-2016 | <p>The Board approved the renewal of DML for following section as per recommendations of panel:</p> <p><u>Section (01):</u></p> <ul style="list-style-type: none"> 1) Tablet (General). <p>The Board further deferred the renewal of DML for following sections as the firm was not ready for inspection:</p> <ul style="list-style-type: none"> 1) Capsule (Cephalosporin). 2) Dry Powder Suspension (Cephalosporin). 3) Sachet (General) <p>The Board further directed the firm not to conduct the manufacturing operations till up-gradation, re-inspection and approval of renewal of above three sections by Central Licensing Board.</p> |
| 13. | <p>M/s Sanna Laboratories, 1019-B, Punjab Small Industrial Estate, Sargodha Road, Faisalabad.</p> <p>DML No. 000329 (Formulation)</p> | 11-03-2016 | <p>The Board approved the renewal of DML for following sections as per recommendations of panel:</p> <p><u>Sections (05): -</u></p> <ul style="list-style-type: none"> 1) Oral Liquid General (Veterinary). 2) Oral Powder General (Veterinary). 3) Liquid Injection General (Veterinary). 4) Vaccine Liquid Injectable (Veterinary). 5) Oral Powder Penicillin (Veterinary). |
| 14. | <p>M/s Medicraft Pharmaceuticals (Pvt) Ltd, 126-B, Industrial</p> <p>DML No. 000390 (Formulation)</p> | 18-03-2016 | <p>The Board approved the renewal of DML for following sections as per recommendations of panel:</p> <p><u>Sections (09): -</u></p> <ul style="list-style-type: none"> 1) Tablet (General). 2) Tablet (Psychotropic). 3) Capsule (Cephalosporin) 4) Dry Suspension (Cephalosporin) 5) Capsule (General) 6) Dry Suspension (General) 7) Dry Powder Injection. 8) Ampoule (General) / Infusion Microdose 9) Injection (Psychotropic) |

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| | | | <p>The Board further deferred the renewal of DML for following section as the firm was not having HVAC ducting in liquid filling room: -</p> <p>1) Syrup (General).</p> <p>The Board further directed the firm not to conduct the manufacturing operations till installation of HVAC, re-inspection and approval of renewal of above section by Central Licensing Board.</p> |
| 15. | <p>M/s Welwrd Pharmaceuticals, Hattar Industrial Estate, Haripur.</p> <p>DML No. 000574 (Formulation)</p> | 16-04-2016 | <p>The Board approved the renewal of DML for following sections as per recommendations of panel:</p> <p>Sections (08): -</p> <p>1) Tablet (General). 2) Capsule (General) 3) Dry Powder Suspension (General) 4) Injection Ampoule / Vial (General) 5) Injection Ampoule (Psychotropic) 6) Injection Vial (Cephalosporin) 7) Injection Dry Powder Vial (General) 8) Sachet (General)</p> |
| 16. | <p>M/s Swan Pharmaceuticals, 11-E, Industrial Triangle, Kahuta Road, Islamabad.</p> <p>DML No. 000669 (Formulation)</p> | 25-02-2016 | <p>The Board approved the renewal of DML for following sections as per recommendations of panel:</p> <p>Sections (04): -</p> <p>1) Tablet (General). 2) Capsule (General) 3) Liquid Ampoule (General) 4) Injection (Psychotropic)</p> |
| 17. | <p>M/s Merck Pharmaceuticals (Pvt) Ltd, F-126, SITE, Karachi.</p> <p>DML No. 000043 (Formulation)</p> | 07-04-2016 | <p>The Board approved the renewal of DML for following section as per recommendations of panel:</p> <p>Section (01): -</p> <p>1) Soft Gelatin Capsule.</p> |

Item No. V Miscellaneous Cases.

Case No. 1 RENEWAL OF DRUG MANUFACTURING LICENSE OF M/S MARION LABORATORIES (PRIVATE) LIMITED, D-43, TEXTILE AVENUE, S.I.T.E, KARACHI.

The case was included in the agenda as under: -

BACKGROUND OF THE CASE: -

The case was placed in 241st meeting of CLB held on 15th May, 2015: -

- M/s Marion Laboratories (Private) Limited was initially granted Drug Manufacturing License (DML) for the manufacturing of Drugs in **LVPs (Infusion)** at premises located at D-43, Textile Avenue, S.I.T.E, Karachi, in 199th meeting of Central Licensing Board held on 23rd – 24th August 2006.
- Accordingly, Firm was issued DML # 000599 (Formulation) for the period of five years w.e.f. 16th September 2006.
- Afterwards, firm submitted application for renewal of DML for the period 16-09-2011 to 15-09-2016 which was well before the period of expiry of validity period of the license. Therefore, license of the firm is continue in force till further orders passed by Central Licensing Board according to Rule 6 of the Drugs (Licensing, Registering & Advertising) Rules 1976 which reproduced as under:-
“Provided that if application for renewal is made before the expiry of the period of the validity of a license, the license shall continue in “force until” orders are passed on such application”
- The application of renewal of the license dated 08th September 2011 was not entertained at the time of submission, due to devolution of the then Ministry of Health.
- After the establishment of the Drug Regulatory Authority of Pakistan in November 2012, the application of renewal of the firm was scrutinized by Licensing Division and shortcomings in the application of renewal of DML were conveyed to the firm on 05th March 2015 according to Rule 5[2A] of the Drugs (Licensing, Registering & Advertising) Rule 1976 which reproduced as under:-
“On receipt of an application of renewal of a license any objection or shortcoming in the application observed by the Central Licensing Board may be notified to the applicant and he shall be given a time period of thirty days for rectification or completion of the application. In case he fails to rectify or complete the application within the specified period, the application may be rejected”
- The shortcomings in the application of renewal of DML conveyed to the firm vide letter dated 05th March 2015, are as under:-
 - - (i) Differential fee of Rs. 32,500/- for renewal of Drug Manufacturing License, as fee revised for renewal of DML is 50,000/-
 - (ii) Names / List of total licensed sections of the firm and proof of grant/approval of sections from Central Licensing Board.
 - (iii) Details of premises including copy of approved layout plan by competent Authority.
 - (iv) Details of proposed production and Q.C Incharge as per checklist enclosed herewith. The technical experts shall possess minimum 10 years experience in the relevant fields after academic qualification according to Rule 16 of Drugs

(Licensing, Registering & Advertising) Rules 1976 after promulgation of S.R.O 470 (I)/98 dated 15-05-1998.

- (v) Copy of latest form 29 issued and attested by Security Exchange commission of Pakistan along with CNIC photocopies of all directors.
 - (vi) An undertaking on letter head of the firm signed by all directors of the firm stating that all information/ documents provided with application of renewal of Drug Manufacturing License is complete and correct and management of firm shall be responsible for hiding or providing wrong information.
 - (vii) Nothing Due certificate issued by Statistical Officer , DRAP, Islamabad, regarding deposition of Central Research fund up to 31-12-2015.
- On 01-04-2015, firm has submitted reply with respect to the letter issued from this Division regarding shortcomings in their application for renewal of DML.
 - In the reply, firm stated that all liable requirements were submitted to Licensing Division in liable period and only liable inspection was supposed to be conducted.
 - According to record of Licensing Division DRAP, Islamabad, the application of renewal of DML of the firm is still incomplete and firm fails to rectify or complete the application within the specified period of 30 days under Rule 5[2A] of the Drugs (Licensing, Registering & Advertising) Rules 1976. Therefore the application of the firm is liable to be rejected.

The case was presented in 241st meeting of the Board wherein the Board decided as under:-
Decision of the Board (M-241):

The Board decided to issue a Show Cause Notice with personal hearing to the firm

Accordingly, Show Cause Notice with personal hearing was issued to the firm and firm was called for personal hearing, please.

Proceedings:

Mr. Amjad Ali, Manager Regulatory Affairs appeared before the Board for personal hearing. He informed that the firm has not received the letter of personal hearing of the instant meeting. However, if a copy of said letter is provided then they will provide the requisite information / documents.

Licensing Division apprised the Board that the statement of firm's representative was not correct as the firm has received the Show Cause notice and also submitted but the information desired is skill lacking. It was added that the letter for personal hearing of the instant meeting of the Board was not sent through ordinary mail but dispatched to the firm through TCS.

Decision of CLB (M-243):

The Board after thorough discussion of the said situation unanimously decided and deferred the matter with final opportunity of Personal Hearing. Board further advised to obtain the tracking of TCS as to verify the claim of firm's representative.

Decision of CLB:

Keeping in view the facts of the case, the Board considered and deferred the matter with final opportunity of Personal Hearing. Board further directed to deliver personal hearing letter through area FID and Courier before one week of CLB meeting.

Accordingly, firm was called for personal hearing.

Proceedings of CLB:

Mr. Imran Saboor, CEO of the firm and Mr. Amjad Manager Regulatory Affairs of the firm's appeared before the Board and presented their point of view that they have already provided the requisite information and obtain acknowledgment of application.

The Board explained then that the firm has not provided requisite information / documents that's why they were issued reminder again.

After such explanation the representative of the firm submitted that their factory is officially closed and they will provide the requisite information / documents after the access to record / documents.

The Law Expert (Member of Board) clarified them that they can access to their record and provide the required information to CLB.

Decision of CLB

Keeping in view the above, the Board considered and decided for final opportunity to provide the requisite information / documents under Rule 5(2A) of the Drugs (Licensing, Registering & Advertising) Rules, 1976.

The Board further directed to inform the firm complete background of the case while communicating decision of CLB.

Case No. 2 ORDERS OF HONORABLE LAHORE HIGH COURT, LAHORE REGARDING WRIT PETITION NO. 10988/2007 FILED BY M/S MICKO INDUSTRIAL CHEMICALS CO. (PRIVATE) LIMITED, 28-KM FERAZEPUR ROAD, LAHORE.

The case was included in the agenda as under: -

Background of the case: -

The case was placed in 241st meeting of CLB held on 15th May, 2015: -

M/s Micko Industrial Chemicals Co. (Private) Limited located at 28-km Ferozepur Road, Lahore submitted application for renewal of DML # 000183 (Formulation) for the period 17-11-2005 to 16-11-2010 for which a panel was constituted on 23-09-2005 for inspection of the firm comprising of following experts / inspectors:-

1. Dr. Ijaz Ahmad, Associate Professor, University of Veterinary and Animal Sciences, Lahore.
2. Area Federal Inspector of Drugs, DCA, Lahore
3. Area Assistant Drugs Controller, DCA, Lahore

The above mentioned panel conducted inspection of the firm for renewal of DML and submitted report on 17-08-2006 wherein panel stated that overall condition of the firm was good. The firm had given undertaking that they would remove the shortcomings pointed out within 15 days. Therefore, the panel is of the opinion that firm may be granted renewal of their Drug Manufacturing License by way of formulation and re-packing.

After receipt of inspection report in this office, the then ADC (L & A) issued a letter to Federal Inspector of Drugs, DCA, Lahore, he stated that firm had submitted an under taking to the panel to rectify the shortcomings as pointed out by the panel, but the compliance report concerning the same had not been received so far therefore area FID was requested to verify the same and submit report within 07 days positively.

The area Federal Inspector of Drugs inspected the premises on 31-10-2007, along with Mr. Ghazanfar Ali Khan, ADC, Lahore to check the rectification of shortcomings pointed out during inspection dated 20-07-2006. The area FID submitted inspection report wherein a number of serious GMP non-compliance were reported and she suggested that production of the firm be stopped and renewal of DML may not be considered in light of critical shortcomings and failure of commitment given by the firm to remove the deficiencies pointed out by the panel during previous inspection.

The area FID sealed the factory and on the form of sealing of the factory she stated that *M/s Micko Industrial Chemicals , 28-km Ferozepur Road, Lahore is sealed due to the violation of Section 27(3) of the Drugs Act, 1976 and various other provisions of the Drugs Act, 1976 and rules framed there under . The owner Mr. Khursheed Alam snatched the samples of drugs taken for the purpose of test analysis from driver Ismail with Form 3. FIR was launched in police station, Kahana and the factory is sealed in the presence of Mr. Ghazanfar, ADC, Javed Iqbal, ASI and Tahir Iqbal, Head Constable .*

The firm was then served a Show Cause Notice on 19th November 2007 by the then Secretary CLB and directed to submit reply of the show cause within 15 days.

A letter dated 17-11-2007 was again received from Ms. Aisha Khalil, the then area FID wherein she informed that owner of the firm had challenged the legal process of panel and the accused Mr. Khurshid Alam Sheikh filed a writ petition No. 10988/2007 in Honorable Lahore High Court Lahore through his counsel requesting the Court to declare the sealing order illegal and for award of cost incurred on this petition. Mr. Justice Syed Hamid Ali Shah issued a one sided interim order dated 07-11-2007 hence suspended the sealing order of panel without hearing the panel, till next hearing and ordered for submission of reply and parawise comments in this regard.

In compliance of court order dated 07-11-2007 she along with Mr. Ghazanfar Ali Khan ADC visited the premises on 14-11-2007 to de-seal the factory and found that the seals were broken by the owner and production of drugs was in process. The position was also brought in to the kind notice of Honorable Court vide etter No. 9067/2007-DCA (L-II) dated 14-11-2007.

On 05th December 2007, a letter was issued to the firm from this office by the then Secretary CLB wherein it was stated that refer to the panel inspection report of the firm conducted by area FID Lahore on 14-11-2007 wherein it was reported that production was in-progress while the conditions of renewal of DML have not been fulfilled as reported by the panel during inspection conducted on 30-10-2007. As this is an offence under Rule 13 of the Drugs (Licensing, Registering & Advertising) Rules 1976, therefore, firm was directed to suspend the production with immediate effect till removal of the deficiencies and re-inspection by a panel and approval of Central Licensing & Registration Board.

Recently, On 23-04-2015, a letter was received from Assistant Registrar , wherein he forwarded the order sheet of Honorable Lahore High Court, Lahore for the Writ Petition # 10988/2007 & 11839/2007. The contents of the order sheets are as under:-

Mr. Bashir Ahmad Tariq, Advocate for the Petitioner.
Ms. Saadia Malik, learned Standing Counsel for Pakistan along with Ayesha Irfan,
Federal Inspector Drugs.

Through this single order I intend to dispose of writ petition Nos. 10988 and 11889 of 2007 as both are based on common facts.

2. In W.P NO. 10988/2007 order dated 30-10-2007 is challenged whereby the factory of the petitioner was sealed for violation of Section 27 (3) and other provisions of the Drugs Act, 1976 and also for the reason that owner of the factory namely Khurshid Alam Sheikh had snatched samples taken from the factory premises by the Federal Drug Inspector.

In other writ petition No. 11889/2007 order for suspension of production is challenged.

3. Facts, which have surfaced after arguments from both sides, are that he inquiry report was being prepared by the Federal Drug Inspector when samples of some illegal drugs were allegedly snatched by the owner of the factory. Statedly, due to violation of the statutory provisions and the illegal act by the owner, the factory premises were sealed. As per learned Standing Counsel's assertions, the factory was de-sealed illegally and production was commenced by the petitioner, therefore, another order for suspension of production was passed.

4. Due to multiplicity of litigation, facts of the case are confused. It is asserted by the petitioner that its factory is sealed and production is suspended whereas learned Standing Counsel submits that the production is being carried out illegally at the sealed premises.

5. Be that as it may, it is settled proposition that this Court cannot look into factual controversies in exercise of its constitutional jurisdiction. For resolution of dispute on facts as well as on legal side, this matter is referred to Central Licensing Board, before which report has already been filed by the Federal Drugs Inspector. The Board shall provide opportunity of being heard to the petitioner and shall pass a speaking order within 45 days positively under intimation to the Deputy Registrar (Judicial) of this Court.
Till decision no coercive measures shall be taken

RECORD AND STATUS OF FIRM IN LICENSING DIVISION

The five years tenure of renewal of DML of the firm for the period 17-11-2005 to 16-11-2010 has been expired without any further orders by Central Licensing Board.

Afterwards, firm submitted application for renewal of DML of the firm for the next five years i.e. from 17-11-2010 to 16-11-2015 for which a panel of experts/inspectors was constituted on 10th March 2011 comprising of following members:-

1. Dr. Farzana Chaudhary, (Member DRB) Director IPS University ad Animal Sciences, Lahore
2. Dr. Noor Muhammad Shah, Deputy Director General (L & A), Islamabad.
3. Dr. Sheikh Akhtar Hussain, Deputy Director General (E & M), DCA, Lahore
4. Area Federal Inspector of Drugs, DCA, Lahore.

The report of the above mentioned panel is still awaited.

It is also submitted here that Ms. Aisha Irfan, Area Federal Inspector of Drugs also updated Licensing Division about the recent orders passed by Honorable Court and case background. she stated that all the action taken by her on the directions of the Central Licensing & Registration Board and as per the Drugs Act, 1976 and rules framed there under, hence, no malafide intentions were involved, and the actions were taken in Good Faith by her. She also requested that she may also be provided with an opportunity to present this case in Central Licensing Board personally.

Therefore, the case is placed before the Licensing Board as per orders of the High Court for further directions in the matter.

The firm, M/s Micko Industrial Chemicals Co. (Private) Limited located at 28-km Ferozpur Road, Lahore and Ms. Aisha Irfan, FID, DRAP, Lahore were called for personal hearing.

Proceedings of the case:

Licensing Division, DRAP apprised the Board that the order sheet of the Honorable Court was received in the Secretariat of the Licensing Division in late hours at Friday on 08th May 2015.

After receipt of the orders of the Honorable Court, Licensing Division processed the case on 11th May 2015 and after approval from competent Authority, letter for personal hearing was issued through Courier to the firm on 13th May 2015.

Area Federal Inspector of Drugs, DRAP, Lahore was contacted telephonically to deliver the copy of the letter of personal hearing to the firm in person but she informed that she couldn't deliver letter because she was at hospital for treatment of illness of his father and her assistant may also not deliver the letter to the firm in person because she is a female. After that, Deputy Director General (E&M), DRAP, Lahore was requested on 14th May 2015 to depute a person from his

office who shall deliver letter to the management of the firm by hand. Accordingly, Mr. Shahid Mehmood, LDC, DRAP, Lahore was sent to deliver the letter of personal hearing to the firm, by hand.

When he reached the location of the firm and contacted the person, Mr. Shoib (son of the owner of the firm) opened the gate and viewed the letter and requested him to be seated so that he may contact his father (Owner of the firm) before receiving the letter.

After half an hour, he came and refused to receive letter of personal hearing from him and stated that his father is not in the factory and currently outside the city. Mr. Shahid Mehmood also given in writing the conversation.

The case was presented in 241st meeting of the Board wherein the Board decided as under:-

Decision of the Board:

The Board after thorough discussion and deliberation decided:-

1. *To provide another opportunity of personal hearing to the firm.*
2. *To deliver letter of personal hearing to the firm by registered post/UMS/ through courier.*
3. *To submit an interim report for the appraisal of Honorable Court, regarding current status of the case in the Central Licensing Board.*

Accordingly, above decision of the Board was conveyed to the firm and letter for personal hearing was issued, please.

Proceedings:

The Board was apprised that the letter for personal hearing was sent to the firm via TCS but no any representative of firm is present for personal hearing.

Decision of CLB (M-243):

Keeping in view the facts of the case, the Board unanimously decided for final opportunity of personal hearing. The Board further directed that letter of personal hearing be sent through TCS, Registered AD, Area FID and also email (if email available). The Honorable Court may again be apprised of the status of the case.

Further Proceedings.

Mr. Khurshid Alam Sheikh, Director Admin for M/s Micko Industrial Chemicals Co. (Private) Limited, Lahore informed the Licensing Division vide letter No. 37/Micko-Lahore dated 01-11-2015 that the orders of single judge in chamber of Lahore High Court dated 23-04-2015 have been challenged before the Division Bench by way of filing inter Court No. 653 & 655, of 2015 and informed that there is hardly any need for personal hearing of the above cases. It is therefore, requested that the matter may be please be protracted till the final disposal of said appeals.

M/s Micko Industrial Chemicals Co. (Private) Limited, Lahore has filed Inter Court Appeal against the judgment passed on W.P. NO. 10/988/2007 in the Honorable Lahore High Court Lahore. The orders of the Honorable Court is as under: -

“For what has been discussed above this Court is of the view that present appeals have not been filed by an authorized person therefore they being incompetently filed are not maintainable and are thus dismissed”.

“For the reasons recorded in judgment of even dated passed in ICA No. 653-2015, this Intra Court appeal is dismissed”. (Announce Date 26-01-2016)

Proceedings:

The Board was apprised of the background of the case and further apprised that M/s Micko Industrial Chemicals Co. (Private) Limited, Lahore had filed Intra Court Appeal against the judgment passed on W.P. NO. 10/988/2007 in the Honorable Lahore High Court Lahore. The orders of the Honorable Court are as under: -

“For what has been discussed above this Court is of the view that present appeals have not been filed by an authorized person therefore they being incompetently filed are not maintainable and are thus dismissed”.

“For the reasons recorded in judgment of even dated passed in ICA No. 653-2015, this Intra Court appeal is dismissed”. (Announce Date 26-01-2016)

The Board was further apprised that after the decision of Intra Court Appeal, M/s Micko Industrial Chemicals Co. (Private) Limited, Lahore has requested for processing the case in the light of previous decision of Honorable Court against writ petition Nos. 10988 and 11889 of 2007.

Decision of CLB:

Keeping in view the facts of the case, the Board unanimously considered and decided for personal hearing of the firm in the light of decision of Honorable Court against writ petition Nos. 10988 and 11889 of 2007.

Accordingly, firm was called for personal hearing.

Proceedings of CLB

Mr. Shehryar Alam S/o Shaikh Khurshid Alam (Son of Director of the firm) and Mr. Bashir Ahmed Tariq, Legal Advisor of the firm appeared before the Board and presented their point of view in a statement as under :-

“I, sheharyar Alam, representative of Mr. Khurshid Alam Shaikh, stated to the panel that kindly grant us some time to rethink upon the issue of withdrawal of civil suit against Ayesha Khalid (FID). I requested the panel to kindly allow us some time to discuss the issue with the Director Khurshid Alam. I believe that it will bring a positive outcome”.

Decision of CLB:

The Board discussed the case in length, keeping in view the case background history and order of Honorable Court. The Board observed that in the instant case Board has heard one sided point of view of the applicant, so an opportunity of hearing shall be given to concerned FID in the interest of Natural Justice; therefore, Board deferred the case for personal hearing of concerned FID in the upcoming meeting of CLB.

The Board further Directed to send an interim report to the Honorable Lahore High Court, Lahore.

Case No.3 THE STATE VERSUS M/S MEDI MARKER'S PHARMACEUTICALS (PVT) LTD., PLOT NO. A-104, S.I.T.E., HYDERABAD.

The case was placed in the agenda as under: -

Division of Drug Licensing has received following Court Orders from Drug Court, Lahore. The same are placed for the consideration of Board, please.

| | |
|---|--|
| THE STATE VERSUS MEDI MARKER'S PHARMACEUTICALS (PVT) LTD | |
| Present: | DDPP for the State Accused Absent. |
| On the last date of hearing N.B.W were issued and the same be forwarded to Deputy Inspector General Hyderabad. The reply from the DIG is received, further marked to the Superintendent of Police Hyderabad, but no reply from the S.P Hyderabad is received as yet. | |
| Let us issued N.B.W of arrest of the accused for 20-11-2015 and again forwarded to the DIG Hyderabad with the direction that the previous warrant were not returned back yet. In these circumstances the attitude of the Sindh Police is highly objection. The copy of the order be sent to the DIG and S.P Hyderabad along with warrants with the direction to get execute the warrant and produce the accused before the court, if he failed then a responsible officer not below the rank of Sub Inspector is directed to appear before. | |
| The N.B.W of arrest of the accused forwarded to the Drug Regulatory Authority of Pakistan through Federal Drug Inspector Lahore with the direction to get execute the warrant of the accused and till the arrest of the accused their license may immediately be suspended and the factory premises of the accused shall be scaled under intimation to this Court. | |
| <u>Announced</u> 03-11-2015 | |
| | S/d Ch. Muhammad Jahangir Chairman |
| S/d Dr. Mubashar Ahmed Butt Member | S/d Farooq Bashir Butt Member |

Proceedings:

The Board was apprised that in pursuance of orders of Honorable Drug Court; Licensing Division has written a letter to DDG (E&M) Lahore for obtaining complete case details from Honorable Drug Court so that case may be processed further.

Decision of CLB (M-245):

Keeping in view the facts of the case, proceeding of the Board and opinion of law expert; the Board considered and decided as under: -

- The Board adopted and endorsed the actions taken by Licensing Division.
- The Board decided to issue a Show Cause notice with personal hearing to the M/s. Medi Marker's Pharmaceuticals (Pvt) Ltd that why their drug manufacturing license may not be suspended in pursuance of the orders of Honorable Drug Court.
- Orders of Honorable Drug Court for sealing of factory premises shall be executed by QA/LT Division through concerned FID.
- The Board directed to send an interim report to the Honorable Drug Court Lahore.

Proceedings:

Accordingly, a Show Cause Notice with Personnel Hearing issued to the firm and a letter for taking further action by Registration Board is conveyed for information / compliance as per the directions of the Honorable Chairman Drug Court, Gilgit Baltistan.

Proceedings of meeting:

The Board was apprised of the case that Honorable Drug Court has passed following orders dated 08-02-2016 as under: -

Present: DDPP for the State.
Accused Munsif Qureshi, Shakoor Sheikh and Raheela Saleem with their counsel.

The accused Raheela Saleem declared as P.O today the learned moved an application and argued that the accused were not properly served and as and when she informed about the N.B.W. she voluntarily surrender himself to appear before the court and ready to furnishing surety bonds. Remaining accused namely Munsif Qureshi and Shakoor Sheikh was regularly appeared before the court, but all of sudden both are seriously ill and it is difficult to travelled from Karachi to Lahore and informed that in future they will careful and appear before the court on each and ever date and requests for withdrawal of warrant of arrest.

Reason seems to be genuine and in the interest of justice the warrants of arrest of the accused already issued by this court is hereby withdrawn and proclamation issued by this court against the accused Raheela Saleem is also withdrawn subject to furnishing surety bonds in the sum of Rs.200,000/- with one surety in the like amount to the satisfaction of this Court.

Copies delivered to the accused. Now to come up for framing of charge on 17-02-2016.

ANNOUNCED

08-02-2016

Ch. Muhammad Jahangir
CHAIRMAN

Dr. Mubashar Ahmed Butt
Member

Farooq Bashir Butt
Member

Decision of CLB:

Keeping in view the above situation and latest court orders, the Board considered and deferred the case till next meeting. Board further directed to ask firm, for the reasons of not appearing before the Board for personal hearing.

Accordingly, firm was called for personal hearing.

Proceedings of CLB

Muhammad Fahim Regulatory Manager of the firm appeared before the Board and presented their point of view in a statement as under:-

“We hereby state that CEO of the company Dr. Abdul Shakoor Usman, Production Manager Mr. Munsif Ali Qureshi and QC Manager Raheela Saleem has appeared before Drug Court Lahore and an instruction to Drug Regulatory Authority for suspension of license was withdrawn by Drug Court Lahore on

February 08, 2016. The same was also delivered by Abdul Rasheed Shaikh FID, Lahore through Drug Court.

For the personal hearing called up by licensing Board on February 22, 2016, we could not personally attend the hearing due to some unavoidable circumstances and feel very sorry for the same and assures the Board for personal presence every time whenever Board will call.

We hereby confirm that we are attending the Drug Court Lahore on each hearing and hopefully our case will be settled very soon from court and orders of the Drug Court Lahore will be provided to Central Licensing Board.

We are very thankful to the Licensing Board giving us a chance for clarification of our position”.

Decision of CLB:

The Board considered and decided to inform the Honorable Drug Court, Lahore regarding the personal hearing and the person appeared before the Board.

Case No.4 M/S EVEREST PHARMACEUTICALS, PLOT NO.124, INDUSTRIAL TRIANGLE, KAHUTA ROAD, ISLAMABAD.

M/s Everest Pharmaceuticals, 124, Industrial Triangle, Kahuta Road Islamabad has submitted the application for renewal of DML No. 000535 by way of formulation on 28-03-2014 on time as due date of renewal of DML was 31-03-2014.

After evaluation of the renewal application of the firm a letter for completion of application for renewal of DML was issued on 7th May, 2014. With reference to above letter the firm has submitted one page reply on 3rd June, 2014 and stated that requisite documents / information have already been provided vide their earlier request letter.

It is mentioned that in available record of Licensing Division, no correspondence received in respect to shortcomings in application for renewal of DML of the firm. On 25th February, 2015 Licensing Division issued another letter for completion of application of renewal of DML to the firm in which mentioned that no correspondence from your side had been received in this Division regarding receipt of documents / information deficient in your application for renewal of DML and advised to the firm to furnish the required information / documents to this office within 20 days of issuance of this letter in case of failure to rectify the application within the specified period, the application for renewal of DML may be rejected by the Central Licensing Board.

On 17th March, 2015 the firm has submitted their one page reply and stated that an FIR in FIA is lodged on misunderstanding of DRAP and their production Manager and Q.C manger were arrested. They will be able to reply the letter of Licensing Division after resolution of the case. They requested to hold any proceeding / any further order till resolution of the case.

Case is submitted for consideration and orders of the Board please.

Proceedings of CLB

Chairman Quality Control (CQC) informed the Board that recently there were two FIRs which have been now quashed by Islamabad High Court.

Decision of CLB:

The Board in the light of information provided by CQC that the said FIRs have been quashed, so Board decided to direct the firm to provide the requisite information / documents for the purpose of renewal of Drug Manufacturing License.

Case No. 5 APPROVAL OF MASER LAYOUT PLAN / AUTHENTICATION / REGULARIZATION OF EXISTING FACILITY, DRUG MANUFACTURING LICENSE NO. 000132 (FORMULATION).

M/s Kohs Pharmaceuticals (Pvt) Ltd, Plot No. P/8, SITE Area, Hyderabad, DML No. 000132 (Formulation), has applied for regularization of layout plan of running facility for their following existing sections which were being licensed before the promulgation of S.R.O. 470/98 dated 15th May 1998 when approval of layout plan was not mandatory: -

| S.# | Section |
|-----|-----------------------|
| 1. | Oral Liquid (General) |

Accordingly, layout plan of firm was approved/regularized/authenticated and following panel was requested to verify the above section of firm as per approved layout plan.

1. Syed Muied Ahmed, Member CLB.
2. Mr. Muhammad Qaisar, Chief Drug Inspector, Sindh.
3. Dr. Abdus Salam Shah, Director, Drug Testing Laboratory, Sindh.
4. Syed Hakim Masood, Area FID DRAP, Karachi.
5. Ms. Ume Laila, Area ADC, DRAP, Karachi.

Accordingly, Panel has inspected the premises and verified the above mentioned section.

Recommendations: -

The firm has improved their liquid section. Therefore, the panel recommends authentication / regularization of existing facility for the liquid syrup section for approval / grant accordingly.

Brief Background: The Board in its 243rd meeting held on Wednesday, 09th September, 2015 had considered and decided as under: -

| | | | |
|----|--|--------------------------|--|
| 3. | M/s. Kohs Pharmaceuticals (Pvt) Ltd., Plot No. P/8, S.I.T.E Hyderabad. | 02-09-2015 (Formulation) | Approved the grant of DML with same DML No. 000132 (Formulation) and with following two sections. <u>Sections (02):</u> 1. Tablet General 2. Capsule General As per panel inspection report, Liquid Section of the firm was under renovation so Board directed the firm to inform the Licensing Division as and when ready. |
|----|--|--------------------------|--|

Case is submitted for consideration and orders of the Board please.

Decision of CLB:

In the light of recommendations of panel of experts, the Board considered the case and approved / regularized the Oral Liquid (General) section of M/s. Kohs Pharmaceuticals (Pvt) Ltd., Plot No. P/8, S.I.T.E, Hyderabad DML No. 000132 (Formulation).

Case No. 6 APPROVAL OF MASER LAYOUT PLAN / AUTHENTICATION / REGULARIZATION OF EXISTING FACILITY, DRUG MANUFACTURING LICENSE NO. 000329 (FORMULATION).

M/s Sanna Laboratories, 1019-B, Punjab Small Industrial Estate, Sargodha Road, Faisalabad, DML No. 000329 (Formulation), has applied for regularization of layout plan of running facility for their following existing sections which were being licensed before the promulgation of S.R.O. 470/98 dated 15th May 1998 when approval of layout plan was not mandatory: -

| S.# | Section |
|------------|-----------------------------------|
| 1. | Oral Powder Penicillin Veterinary |

Accordingly, layout plan of firm was approved/regularized/authenticated and following panel was requested to verify the above section of firm as per approved layout plan.

1. Dr. Ikram ul Haq, Member CLB.
2. Dr. Qurban Ali, Director General, NVL, Islamabad.
3. Mr. Rana Abdul Mateen Khan, Secretary PQCB, Lahore.
4. Mr. Ajmal Sohail Asif, FID, DRAP, Lahore.

Mrs. Saira Naeem, ADC DRAP, Lahore is not mentioned in report but was member of above panel.

Accordingly, Panel has inspected the premises and verified the above mentioned section.

Recommendations: -

The panel of inspectors recommends the renewal of DML bearing No. 000329 issued in favor of M/s Sanna Laboratories, 1019-B, Punjab Small Industrial Estate, Sargodha Road, Faisalabad and the approval / regularization oral powder section (Penicillin) as per approved amendments.

Case is submitted for consideration and orders of the Board please.

Decision of CLB:

In the light of recommendations of panel of experts, the Board considered the case and approved / regularized the Oral Powder Penicillin Veterinary section of M/s Sanna Laboratories, 1019-B, Punjab Small Industrial Estate, Sargodha Road, Faisalabad DML No. 000329 (Formulation).

Case No.7 CHANGE OF THE MANAGEMENT OF M/S THERAMED PHARMACEUTICALS (PVT) LTD, 45-KM, MULTAN ROAD, LAHORE, DML NO.000696 (FORMULATION).

M/s. Theramed Pharmaceutical (Pvt) Ltd, 45-KM, Multan Road, Lahore, DML No.000696 (Formulation) has applied for change of management with a fee of Rs.50,000/- duly retained by Statistical Officer DRAP Islamabad.

The management of the firm has been partially changed as per Form 29 issued by Security Exchange Commission of Pakistan where this company is registered under:-

| Old Management | New Management |
|--|---|
| Mr. Abdul Ghaffar S/o Muhammad Sharif CNIC No. 35202-1103534-9. | Mr. Waqas Fazal S/o Fazal Hussain CNIC No. 35202-2936828-9 (New). |
| Mrs. Kausar Jabeen W/o Abdul Ghaffar CNIC No. 35202-8846976-0 | Ch. Muhammad Irshad S/o Muhammad Shafi CNIC No. 35202-1660976-3 (New). |

Case is submitted for consideration and orders of the Board please.

Decision of CLB:

The Board considered and approved the change of title of the firm from M/s Theramed Pharmaceutical to M/s Theramed Pharmaceutical (Pvt) Ltd; and further acknowledged the change of management from old to new as per Form 29 issued by Security Exchange Commission of Pakistan as under: -

| Old Management | New Management |
|--|---|
| Mr. Abdul Ghaffar S/o Muhammad Sharif CNIC No. 35202-1103534-9. | Mr. Waqas Fazal S/o Fazal Hussain CNIC No. 35202-2936828-9 (New). |
| Mrs. Kausar Jabeen W/o Abdul Ghaffar CNIC No. 35202-8846976-0 | Ch. Muhammad Irshad S/o Muhammad Shafi CNIC No. 35202-1660976-3 (New). |

Case No.8 **CHANGE OF THE MANAGEMENT OF M/S PRIX PHARMACEUTICALS (PVT) LTD, LAHORE, DML NO.000587 (FORMULATION).**

M/s. Prix Pharmaceutical (Pvt) Ltd, Plot No.5, Pharmacy, 30-KM Multan Road, Lahore, DML No.000587 (Formulation) has applied for change of management with a fee of Rs.50,000/- duly retained by Statistical Officer DRAP Islamabad.

The management of the firm has been partially changed as per Form 29 issued by Security Exchange Commission of Pakistan where this company is registered under:-

| Old Management | Retiring Management | New Management |
|------------------------|------------------------------|---------------------------|
| 1. Syed Hassan Mehdi. | 1. Mr. Muhammad Hassan Mehdi | 1. Syed Baqar Abbas Naqvi |
| 2. Mr. Sajjad Mehdi. | | 2. Syed abid Abbas. |
| 3. Dr. Syed Abdi Abbas | | 3. Mr. Sajjad Mehdi. |

Case is submitted for consideration and orders of the Board please.

Decision of CLB:

The Board considered and acknowledged the change of management from old to new as per Form 29 issued by Security Exchange Commission of Pakistan as under: -

| Old Management | Retiring Management | New Management |
|------------------------|------------------------------|---------------------------|
| 1. Syed Hassan Mehdi. | 1. Mr. Muhammad Hassan Mehdi | 1. Syed Baqar Abbas Naqvi |
| 2. Mr. Sajjad Mehdi. | | 2. Syed abid Abbas. |
| 3. Dr. Syed Abdi Abbas | | 3. Mr. Sajjad Mehdi. |

Case No.9 CHANGE OF THE LEGAL STATUS / TITLE OF M/S WIMITS PHARMACEUTICALS, LAHORE, DML NO.000789 (FORMULATION).

M/s. Wimits Pharmaceuticals Plot No. 129, Sunder Industrial Estate, Raiwind Road, Lahore, DML No.000789 (Formulation) has applied for change of legal status / title of the firm with a fee of Rs.50,000/- duly retained by Statistical Officer DRAP Islamabad as under: -

| Previous legal Status / Title | New legal Status / Title (as per Form-29) |
|--|---|
| M/s. Wimits Pharmaceuticals, Plot No. 129, Sunder Industrial Estate, Raiwind Road, Lahore, DML No.000789 (Formulation), (Partnership firm) | M/s. Wimits Pharmaceuticals (Pvt) Ltd, Plot No. 129, Sunder Industrial Estate, Raiwind Road, Lahore, DML No.000789 (Formulation), (Private Limited company) |

Case is submitted for consideration and orders of the Board please.

Decision of CLB:

The Board considered and approved the change of title / legal status of the firm from M/s. Wimits Pharmaceuticals, Plot No. 129, Sunder Industrial Estate, Raiwind Road, Lahore, DML No.000789 (Formulation) (partnership firm) to M/s. Wimits Pharmaceuticals (Pvt) Ltd, Plot No. 129, Sunder Industrial Estate, Raiwind Road, Lahore, DML No.000789 (Formulation); as per Form 29 issued by Security Exchange Commission of Pakistan.

Case No.10 CHANGE OF THE TITLE / NAME OF M/S SAGULL SURGICAL COTTON BANDAGE INDUSTRY, JHANG, DML NO.000482 (FORMULATION).

M/s. Seagull Surgical Cotton Bandage Industry, Tower Point Beg Colony Gojra Road, Jhang, DML No.000482 (Formulation) has applied for change of **Title / Name** of the firm with a fee of Rs.50,000/- duly retained by Statistical Officer DRAP Islamabad as under: -

| Previous Title / Name | New legal Title / Name |
|---|---|
| M/s. Seagull Surgical Cotton Bandage Industry, Tower Point Beg Colony Gojra Road, Jhang, DML No. 000482 (Formulation) | M/s. Seagull Pharma, Tower Point Beg Colony Gojra Road, Jhang, DML No. 000482 (Formulation) |

Case is submitted for consideration and orders of the Board please.

Decision of CLB:

The Board considered and approved the change of title / name of the firm as under: -

| Previous Title / Name | New legal Title / Name |
|---|---|
| M/s. Seagull Surgical Cotton Bandage Industry, Tower Point Beg Colony Gojra Road, Jhang, DML No. 000482 (Formulation) | M/s. Seagull Pharma, Tower Point Beg Colony Gojra Road, Jhang, DML No. 000482 (Formulation) |

Case No.11 CHANGE OF THE MANAGEMENT OF M/S CKD PHARMACEUTICALS PAKISTAN (PVT) LTD, KARACHI, DML NO.000144 (FORMULATION).

M/s. CKD Pharmaceutical Pakistan (Pvt) Ltd, Plot No, DML No.000144 (Formulation) has applied for change of management with a fee of Rs.50,000/- duly retained by Statistical Officer DRAP Islamabad.

The management of the firm has been partially changed as per Form 29 issued by Security Exchange Commission of Pakistan where this company is registered under:-

| Old Management | New Management |
|--|---|
| <ol style="list-style-type: none">1. Mr. M. Azam, C.E.O2. Mr.Tafseer-ul-Islam, Director3. Col (R) Tauqir Islam | <ol style="list-style-type: none">1. Mr. Ahsan Sultan , C.E.O CNIC No. 42201-3110080-92. Mr. Shabab Ahmed, Director. CNIC No. 42301-0887778-33. Mr. Anas Aultan, Director and Company Secretary. CNIC No. 42201-0775491-9 |

Case is submitted for consideration and orders of the Board please.

Decision of CLB:

The Board considered and acknowledged the change of management from old to new as per Form 29 issued by Security Exchange Commission of Pakistan as under: -

| Old Management | Retiring Management | New Management |
|--|--|---|
| <ol style="list-style-type: none">1. Mr. M. Azam, C.E.O2. Mr.Tafseer-ul-Islam, Director3. Col (R) Tauqir Islam | <ol style="list-style-type: none">1. Mr. M. Azam, C.E.O2. Mr.Tafseer-ul-Islam, Director3. Col (R) Tauqir Islam | <ol style="list-style-type: none">1. Mr. Ahsan Sultan , C.E.O CNIC No. 42201-3110080-92. Mr. Shabab Ahmed, Director. CNIC No. 42301-0887778-33. Mr. Anas Aultan, Director and Company Secretary. CNIC No. 42201-0775491-9 |

Case No.12 M/S CHEMI WORLD (PVT) LIMITED ,PESHAWAR, DML NO. (FORMULATION).

M/s Chemi world (Pvt) Limited ,Peshawar was granted DML by way of Basic Manufacturing in 189th meeting of CLB held on 19th -20th april 2005 ,w.e.f 11-05-2005 to 10-05-2010 for 17 APIs (page 141/corr). On 28th -03-2006 firm granted approval of additional API ,i-e Iron (III) Hydroxide Polymaltose complex and on 11 – 07-2006 firm was granted API (Iron (III) hydroxide Polymaltose Complex (Syrup Grade).

This office has issued a letter to DDG (E&M) Peshawar that renewal of DML of firm is due with effect from 11-05-2010 and panel for DML renewal application was constituted(Page 205/Corr). But no report has been received yet.

The firm has submitted DML renewal application dated 15-07-2015 which is submitted after the expiry of validity (10-05-2015) of DML by way of Formulation. As per rule 6 of Drugs (Licensing, Registering & Advertising) Rules, 1976 “**A license issued under this chapter , unless earlier suspended or cancelled , be in force for a period of five years from the date of issue and may thereafter be renewed for periods of five years at a time: provided that if application for renewal is made before the expiry of the period of validity of license , the license shall continue in force until orders are on such application . provided further that if an application for renewal is made after the expiry of the period of validity of a license but within sixty days of its expiry, the license shall continue to be in force on payment of additional surcharge of rupee five thousand for each day the application is delayed and thereafter until orders are passed on such application.**”

Now the firm has submitted an application for Re grant of DML by way of formulation, also the firm admitted that they did not submitted the DML renewal application with in the validity of DML due to their domestic problems/sever terrorism in KPK , our Industrial estate near with F.R boundary line.

Case is submitted for consideration and orders of the Board please.

Decision of CLB:

The Board considered and decided that the Drug Manufacturing License of the firm M/s Chemi world (Pvt) Limited, Peshawar is no more valid. The afresh application submitted by firm be treated as afresh application for grant of Drug Manufacturing License and Licensing Division shall process it accordingly.

Case No.13 ACKNOWLEDGMENT OF SECTIONS OF M/S UNEXOLABS (PVT) LTD, LAHORE, DML NO.000065 (FORMULATION).

M/s Unexolabs (Pvt) Ltd, 9.5-KM, Sheikhpura Road, Lahore has submitted an application for acknowledgment of their following sections as under: -

1. Tablet (General)
2. Tablet Narcotic / Psychotropic section.
3. Anti T.B. Section.
4. Capsule (General)
5. Steroid Tablet Section.
6. Tablet (Quinolone)
7. Capsule (Cephalosporin)
8. Capsule (Penicillin)
9. Sulphonamide Seciton

It is submitted that the case of M/s Unexolabs (Pvt) Ltd, 9.5-KM, Sheikhpura Road, Lahore, DML No. 000065 by way of formulation was approved in 237th meeting of CLB held on 1st October, 2014 for renewal of Drug Manufacturing License for the period 13-06-2014 to 12-06-2019. The above mentioned sections were also confirmed from the evaluation form which were submitted along with inspection report.

Case is submitted for consideration and orders of the Board please.

Decision of CLB:

The Board considered and decided that the sections shall be verified from the record and verified sections shall be conveyed to the firm. And firm shall be directed for regularization of rest of sections.

Case No.14 ACKNOWLEDGMENT / REGULARIZE OF SECTIONS OF M/S NOA HEMIS PHARMACEUTICALS, KARACHI, DML NO.000525 (FORMULATION).

The case of M/s Noa Hemis Pharmaceuticals, Plot No. 154 Sector 23 Korangi Industrial Area Karachi DML No. 000525 (Formulation) was approved in 240th meeting of CLB held on 6th March, 2015 for renewal of DML with following sections and decided as under: -

Decision of CLB

| | | | |
|----|--|-----------------------------|---|
| 1. | M/s Noa Hemis Pharmaceutical, Plot No.154, Sector 23, Korangi Industrial Area, Karachi. | DML No.000525 (Formulation) | Approved the Grant of Renewal of DML The Board was apprised that the firm possesses the following sections, however firm does not possess the formal letter from CLB of these sections: <ol style="list-style-type: none">1. Tablet (General)2. Capsule (General)3. Tablet (Antibiotics)4. Capsule (Antibiotics)5. Powder & Granules (Sachet)6. Cream/Ointment - General7. Cream/Ointment (Steroidal)8. Oral Liquid (Syrup/Suspension)9. Veterinary (Dry Powder General)10. Veterinary (Dry Powder Antibiotic)11. Veterinary (oral/syrup liquid) The Board decided that the firm be directed to get regularized the master layout plan of these sections for obtaining formal letter of above sections. |
|----|--|-----------------------------|---|

Accordingly, above decision of the Board was conveyed to the firm for regularized their master layout plan of above sections. The firm has submitted their reply and requested that the CLB in its 240th meeting has approved the above section. The firm has furnished photocopies of his renewal inspection report and say that the panel approved above mentioned sections in the evaluation report.

It is stated that the above sections was also approved in 180th meeting of CLB held on 3rd & 4th September, 2003 as under: -

Tablet (General), Tablets & Powders (Antibiotic / Quinolone), Capsules (Antibiotic), Powder/Granules Sachet Filling, Liquid, Cream & Ointment, Liquid & Powder (Veterinary).

The firm have approved layout plan from the then CQC, DDC (R-II) and DDC (L&A).

Now the firm is requested to regularize the above sections and issue us the formal letter of above sections, please.

Case is submitted for consideration and orders of the Board please

Decision of CLB:

The Board considered that the CLB has already approved Tablet (General), Tablets & Powders (Antibiotic / Quinolone), Capsules (Antibiotic), Powder/Granules Sachet Filling, Liquid, Cream & Ointment, Liquid & Powder (Veterinary) sections in its 180th meeting held on 3rd & 4th September, 2003 but formal approval letter was not issued. Later on during renewal of DML the panel of inspectors have witnessed the Tablet (General), Capsule (General), Tablet (Antibiotics), Capsule (Antibiotics), Powder & Granules (Sachet), Cream/Ointment – General, Cream/Ointment (Steroidal), Oral Liquid (Syrup/Suspension), Veterinary (Dry Powder General), Veterinary (Dry Powder Antibiotic) and Veterinary (oral/syrup liquid) sections of the firm.

Keeping in view the above situation, the Board considered and acknowledge the following sections in the name of M/s Noa Hemis Pharmaceutical, Plot No.154, Sector 23, Korangi Industrial Area, Karachi: -

Sections (11)

1. Tablet (General)
2. Capsule (General)
3. Tablet (Antibiotics)
4. Capsule (Antibiotics)
5. Powder & Granules (Sachet)
6. Cream/Ointment - General
7. Cream/Ointment (Steroidal)
8. Oral Liquid (Syrup/Suspension)
9. Veterinary (Dry Powder General)
10. Veterinary (Dry Powder Antibiotic)
11. Veterinary (oral/syrup liquid)